A-72 A-101-L

JOHN J. CASEY

June 28, 1961

MORRIS ROZAR ANDY BAUMERT

Mr. Alfred J. Duncan, Secretary
State Board of Pharmacy
1028 E. McDowell Road
Phoenix, Arizona

I Concur CLARK KENNEDY

Dear Mr. Duncan:

You have requested our opinion as to whether or not the following regulation can be enforced by the Arizona State Board of Pharmacy:

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"Regulation controlling sale of dangerous drugs

Any drug that does not require prescription, but is of such a nature, or the condition for which it is intended is of such nature, that oral directions, caution or warning should be given, in addition to the printed direction, caution or warning on the label, shall be dispensed under the supervision of a registered pharmacist in a licensed pharmacy, dispensary or drug store.

Such drugs shall include, unless otherwise exempted by the Board of Pharmacy:

- 1. Parenterals.
- 2. Any drug that is changed from prescriptiononly legend to over-the-counter status by the Federal Food and Drug Administration.
- 3. Any drug bearing a warning or caution label.
- 4. Any vitamin that claims to have therapeutic properties."

The powers and duties of the Board are set forth in A.R.S. 32-1904, which we quote in part:

"§32-1904. Powers and duties

The board may:

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61-98-L Mr. Alfred J. Duncan, Secretary June 28, 1961 State Board of Pharmacy Page Two Make by-laws, rules and regulations necessary for the protection of the public appertaining to the practice of pharmacy and the lawful performance of its duties. The applicable statute to determine the validity of the above regulation is A.R.S. §32-1964, which states as follows: "§32**-**1964. Dangerous drugs defined and enumerated; restriction on sale: addition to list The term 'dangerous drug' means any drug Α. or device sold at retail, the label of which bears a statement that it is to be dispensed or sold only by or on the prescription of a physician, denist or veterinarian. The sale of any such drug or device is unlawful unless it is sold on a prescription of a member of the medical, dental or veterinary profession who is licensed by law to administer such drug or device. The term 'dangerous drug' includes, but is not limited to, the following: (Emphasis supplied) 1. Any hypnotic drug. 'Hypnotic drug' includes acetylurea derivatives, barbituric acid derivatives, chloral, paraldehyde, phenylhydantoin derivatives, sulfonmethane derivatives or any compounds or mixtures or preparations that may be used for producing hypnotic effects. 2. Aminopyrine, or compounds or mixtures thereof. Amphetamine, desoxyephedrine, or compounds or mixtures thereof except preparations for use in the nose and unfit for internal use. 4. Cinchophen, neocinchophen, or compounds or mixtures thereof. Diethyl-stilbestrol, or compounds or mixtures

thereof.

61-98-6 Mr. Alfred J. Duncan, Secretary June 28, 1961 State Board of Pharmacy Page Three 6. Ergot, cotton root, or their contained or, derived active compounds or mixtures thereof, and except preparations designed for the purpose of treating animals or poultry, and so labeled. The word 'animals' does not include homo sapiens. 7. Oils of croton, rue, savin or tansy or their contained or derived compounds or mixtures thereof. 8. Sulfanilamide or substituted sulfanilamides, or compounds or mixtures thereof, except preparations for topical application only containing not more than five per cent strength, and except preparations designed for the purpose of treating animals or poultry. and so labeled. The word 'animals' does not include homo sapiens. 9. Thyroid and its contained or derived active compounds or mixtures thereof. The board of pharmacy may make such additions to the list of dangerous drugs set forth in subsection A. of this section as recommended or designated under the provisions of the federal food, drug and cosmetic act. Notification of such additions shall be sent to all licentiates in pharmacy by the secretary of the board within thirty days from the adoption of such additions." (Emphasis supplied) A.R.S. §32-1964 has specifically defined a dangerous drug to be any drug or device sold at retail, the label of which bears a statement that it is to be dispensed or sold only by or on the prescription of a physician, dentist or veterinarian. The statute further sets forth, by name, certain dangerous drugs and specifically provides that the Board of Pharmacy may make additions to this list of named dangerous drugs as recommended or designated under the provisions of the Federal Food. Drug and Cosmetic Act. Now by regulation the Arizona State Board of Pharmacy says that any drug that does not require prescription but is of

Now by regulation the Arizona State Board of Pharmacy says that any drug that does not require prescription but is of such nature, or the condition for which it is intended is of such nature, that oral directions, caution or warning should be given, in addition to the printed direction, caution or warning on the label is dangerous and to this regulation the Board has listed certain drugs not named within the statute

61-98-L Mr. Alfred J. Duncan, Secretary June 28, 1961 State Board of Pharmacy Page Four as dangerous, nor to our knowledge recommended or designated as dangerous by the Federal Food, Drug and Cosmetic Act. It is stated in 42 Am. Jur. §53 and we quote, as follows: "Since the power to make regulations is administrative in nature, legislation may not be encated under the guise of its exercise by issuing a 'regulation' which is out of harmony with, or which alters, extends, or limits the statute being administered or which is inconsistent with the expression of the law makers intent in other statutes." From the foregoing, it is our opinion that this regulation alters and extends the statutory definition of a dangerous drug beyond the intent of the legislature and is therefore invalid. Very truly yours, ROBERT W. PICKRELL The Attorney General JOHN J. CASEY Assistant Attorney General JJC:c